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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,662	01/30/2002	Michael Mullican	VPI/99-07 CON US	6730
7590 07/15/2004			EXAMINER	
Tina Powers VERTEX PHARMACEUTICALS INC. 130 Waverly Street Cambridge, MA 02139-4242			ROBINSON, BINTA M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/060,662

Applicant(s)

MULLICAN ET AL.

Examiner

Binta M Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/23/02</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### **Election/Restrictions**

The Markush group set forth in the claims includes both independent and distinct inventions, and patentable distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentable distinct compounds, also far too numerous to list individually. ***For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121***, wherein a Group is a set of patentable distinct inventions of a broad statutory category (e.g. compounds, methods of use, methods of making, etc.):

- I. Claims 1-15, 26 (in part), are drawn to products of the formula depicted in claim 1, and composition, classified in various subclasses of classes 514, 544, 546, 548, and 549.
- II. Claims 16-25, are drawn to a method of use for the compounds of the formula (I) classified in various subclasses of class 514.

If Group II is elected, then election of one of the following methods of use is required:

- A. Method of treating trigeminal neuralgia
- B. Method of treating glossopharyngeal neuralgia
- C. Method of treating Bell's Palsy
- D. Method of treating myasthenia gravis
- E. Method of treating muscular dystrophy

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- F. Method of treating muscle injury
- G. Method of treating progressive muscular atrophy
- H. Method of treating progressive bulbar inherited muscular atrophy
- I. Method of treating herniated, ruptured, or prolapsed intervertebrae disk syndrome
- J. Method of treating cervical spondylosis
- K. Method of treating plexus disorders
- L. Method of treating thoracic outlet destruction syndromes
- M. Method of treating peripheral neuropathies
- N. Method of treating porphyria
- O. Method of treating other peripheral myelin disorders
- P. Method of treating Alzheimer's disease
- Q. Method of treating Guillain-Barre syndrome
- R. Method of treating Parkinson's disease and other Parkinsonian disorders
- S. Method of treating ALS
- T. Method of treating Tourette's syndrome
- U. Method of treating multiple sclerosis
- V. Method of treating other central myelin disorders
- W. Method of treating stroke and ischemia associated with stroke
- X. Method of treating neural paropathy
- Y. Method of treating other neural degenerative diseases
- Z. Method of treating motor neuron diseases

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- A1. Method of treating sciatic crush
- A2. Method of treating neuropathy associated with diabetes
- A3. Method of treating spinal cord injuries
- A4. Method of treating facial nerve crush and other trauma
- A5. Method of treating chemotherapy and other medication-induced

neuropathies

- A6. Method of treating Huntington's disease

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

**Where an election of any one of Group I is made, an election of a single compound is further required** including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent f R1, for example OH or aryl and

each subsequent variable position. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed

to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

***Rationale Establishing Patentable Distinctiveness Within Each Group***

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group),

i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

***The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:***

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed could be used in a materially different process of using that product as demonstrated throughout the specification and in claim 21 which are directed to several different methods of using the product, for example treating trigeminal neuralgia, Alzheimer's disease, and sciatic crush.



In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

### ***Advisory of Rejoinder***

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR

1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

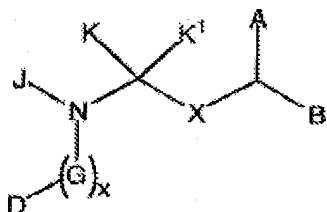
The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

### ***Response to Restriction***

During a telephone conversation with Applicants' representative, Nandakumar Govindaswamy on 7/6/04, an election was made **with** traverse to **Group I**, claims 1-15, and 26 in part directed to products of Formula I, and the specific compound 106, on



(I)

page 33 of the specification. As previously stated in the restriction requirement, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims and method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Status of the Claims***

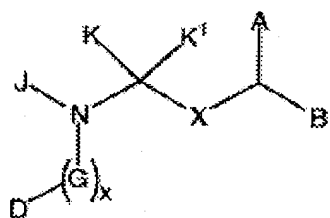
Claims 1-26 are pending in this application. Claims 1-26 ( in part), 16-25 as well as the unelected portions of claims 1-15 and 26 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected

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invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:

Compounds of formula ,



(I)

depicted in claim 1, wherein:

X is  $-\text{CH}_2\text{CH}_2-$ ,  $-\text{C}(\text{OH})\text{CH}_2-$ ,  $-\text{CH}_2\text{C}(\text{OH})-$ ,  $-\text{CH}(\text{F})\text{CH}_2-$ ,  $-\text{C}(\text{F})_2\text{CH}_2-$ , A and B are 9C1-C10)-straight or branched alkyl wherein one or 2 hydrogen atoms are replaced with E which is a partially saturated or unsaturated, or aromatic monocyclic 6 membered ring containing 5 carbons and 1 nitrogen, J and K taken together with the nitrogen and carbon atom to which they are respectively bound form a 5 membered heterocyclic ring wherein 1 to 4 hydrogen atoms in said heterocyclic ring are optionally and independently replaced with (C1-C6)-straight or branched alkyl, (C2-C6)-straight or branched alkenyl or alkynyl or hydroxyl, G is  $-\text{S}(\text{O})_2$ ,  $-\text{C}(\text{O})-$ ,  $-\text{S}(\text{O})_2-\text{Y}-$ ,  $-\text{C}(\text{O})-\text{Y}-$ ,  $-\text{C}(\text{O})-\text{C}(\text{O})-$ , or  $-\text{C}(\text{O})-\text{C}(\text{O})-\text{Y}$ , Y is oxygen or N(R<sub>6</sub>), wherein R<sub>6</sub> is hydrogen, (C1-C6)-straight or branched alkyl, (C3-C6) -straight or branched alkenyl or alkynyl, D is E which

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is a monocyclic aromatic ring system wherein said ring comprises 5-7 ring atoms selected from C, wherein 1 to 4 hydrogen atoms in E are optionally and independently replaced with halogen, hydroxyl, hydroxymethyl, nitro, SO<sub>3</sub>, trifluoromethyl, trifluoromethoxy, (C1-C6)-straight or branched alkyl, (C2-C6)-straight or branched alkenyl..

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-15, and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl; piperidinyl; imidazolyl, pyrrolidinyl etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e.class 544 subclass 224(+) (diazines), class 546 subclass 184(+) (piperdines), 546 subclass 249(+) (pyridines) etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

#### **Claim Rejections and objections**

In Claim 14, line 4, page 76 of the claims filed 1/20/02, the phrase "such as" is ambiguous because the metes and bounds of the truncated derivatives that the neurotrophic factors can be is not delineated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 26 in part are rejected under 35 U. S. C. 112, first paragraph, because the specification, while being enabling for compounds of formula I that are specifically named, ( e. g. Compound 198 on page 38 of the specification), does not reasonably provide enablement for an instantly claimed compound wherein the compound is a "derivative" thereof of the compound of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

#### **The Nature of the Invention**

The nature of the invention in claims 1-15 and 26 is producing pharmaceutical grade derivatives of compounds of the formula I.

#### **The state of the Prior Art**

The state of the prior art is that there are numerous derivatives of the compounds of formula I. These derivatives are aliphatic, aromatic, carbocyclic, heterocyclic, etc. compounds. US 5264204 teaches the N-oxide derivatives of compounds of formula I.

**The predictability or lack thereof in the art**

There would be little predictability in the art of which modifications may be made to a compound of formula I, which would retain its capability as a pharmaceutical grade compound. US Patent 5264204 teaches the N-oxide derivatives of the instant compounds as agents used for enhancing magnetic resonance imaging. The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

**The amount of direction or guidance present**

The term derivative may encompass a great number of compounds related to the compounds of formula I, however, without some guidance as to what changes may be made to the instant compound, there would be little predictability in making and/or using such "derivatives". For example, there is no guidance as to what modifications may be made to the specific compound to obtain a derivative. One skilled in the art would not expect any modifications of the instant compound, which is of pharmaceutical grade.

**The presence or absence of working examples**

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The only presence of a working example is the example on pages 33-68 for the preparation of the instant compound of formula I. There are not other working examples for any other derivatives listed in the specification.

**The breadth of the claims**

The breadth of the claims is that the derivative of the instant compound could include an unlimited number of compounds that are heterocyclic, non-heterocyclic, aliphatic, etc.

**The quantity of experimentation needed**

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what listed derivatives would be prepared by the method described and would furthermore then have to determine whether the claimed process would produce pharmaceutical grade compounds of the formula I.

**The level of skill in the art**

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which derivatives exhibit the desired pharmacological activity. Thus the specification fails to provide sufficient support of the broad use of the term "derivative" because no formula is provided. As a result necessitating one of skill to perform an exhaustive search for which derivatives can be prepared in order to practice the claimed invention.



Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ 2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which derivatives can be prepared by the method encompassed in the instant claims, with no assurance of success.

The specification says that a "pharmaceutically acceptable derivative thereof" can denote a "salt" or "ester" or "salt of such ester", however, the specification does not define what these esters or salts of esters are. Therefore, this rejection can be overcome by changing the phrase "pharmaceutical acceptable derivatives thereof" in line 3, page 70 of the claims filed 1/30/02 to "pharmaceutical acceptable salt" which has support in the specification on page 24, line 14.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 1-15, and 26 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 6, page 72, of the claims filed 1/20/02 and all other occurrences throughout claims 2-15, and 26, the term "comprises" is indefinite for a compound claim because it is open

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ended language. A compound claim must contain language that is not open-ended but more limiting, such as "consisting of".

The elected species is allowable.

The IDS filed 8/23/02 has been considered.

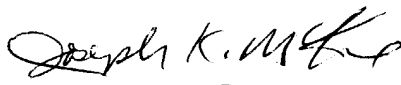
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR  
July 9, 2004

  
JOSEPH K. MCKANE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600